Drug attrition

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Agenda

- 13.00-13.45: Pharmaceutical drug development
- 13.45-14.00: Break
- 14.00-14.45: Drug attrition
- 14.45-15.00: Break
- 15.00-16.00: Exercise

Drug development in the hands of commercial companies

- Drug development is risky, expensive and with long timelines
- Drug companies look for a commercial market and a fair chance of success

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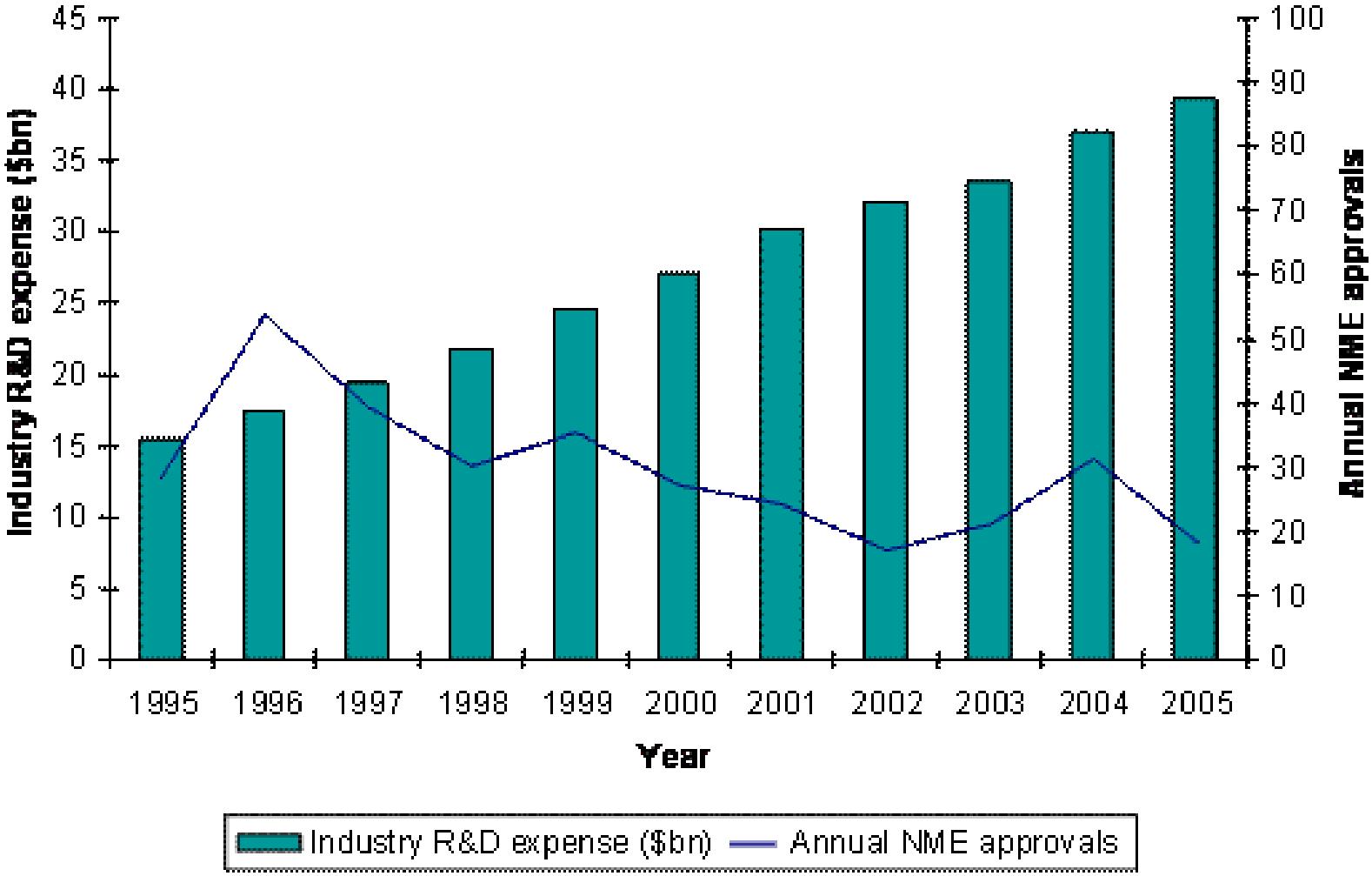
R&D expenditure versus annual NME approvals, 1995-2005



- From: Winning R&D Productivity Strategies. Source: Business Insights; PhRMA; FDA
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Challenges for drug companies

- Income has decreased
- Productivity has decreased
- Shorted period of exclusivity for pharmaceutical products
- Pricing more difficult
- Ethical issues

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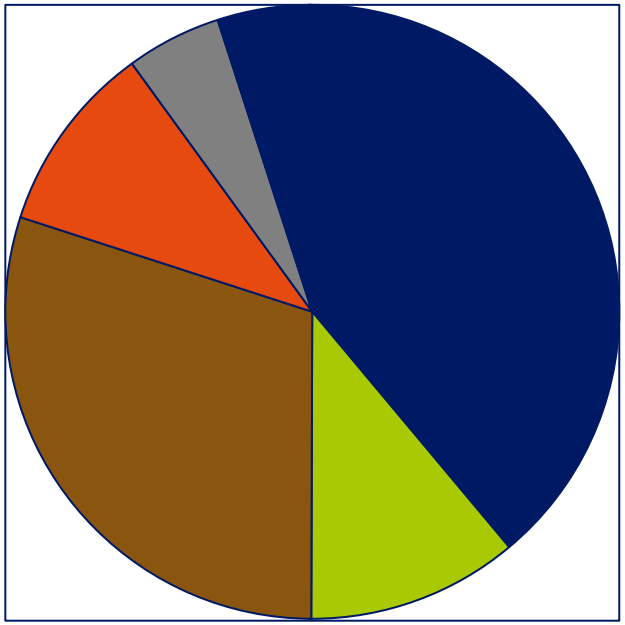
Main reasons for attrition in drug development



Nature Reviews Drug Discovery 2, 192-204 (March 2003)

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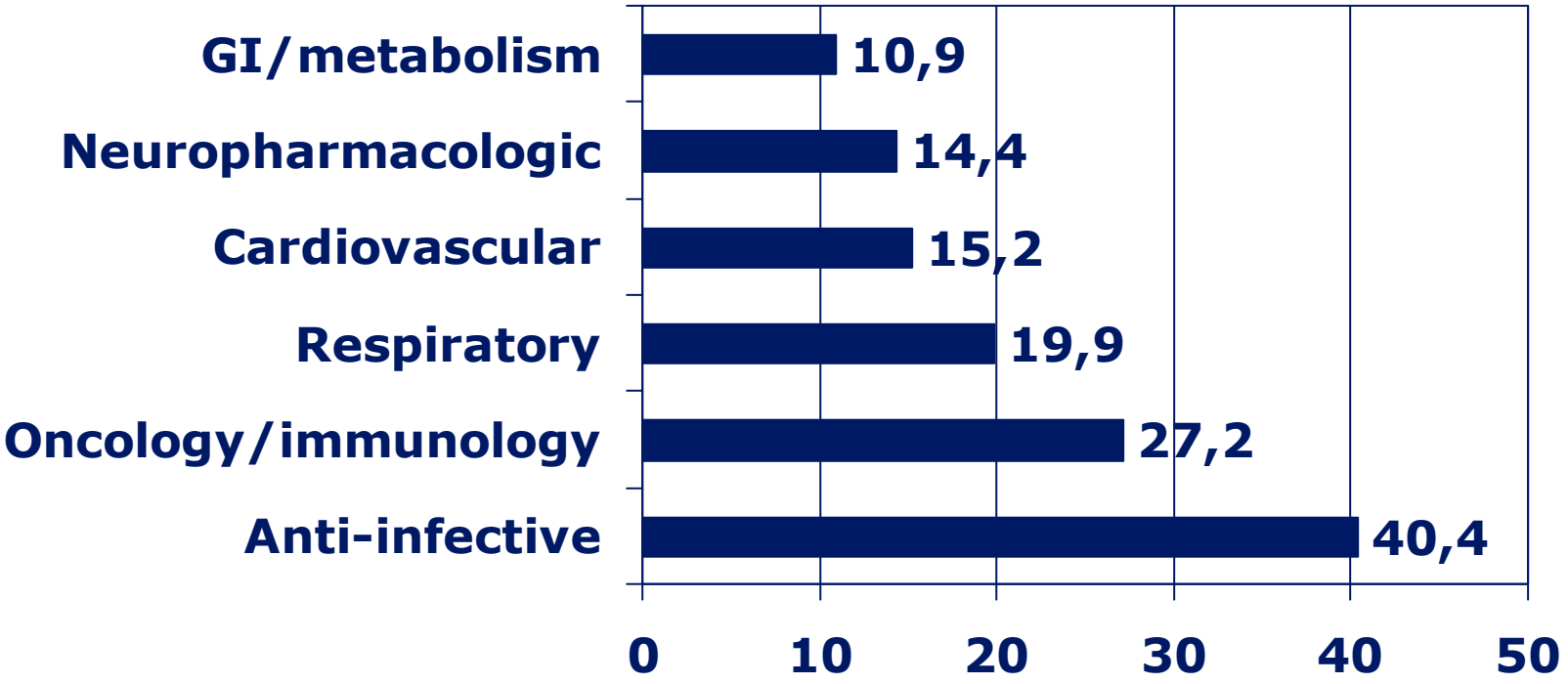
Approval Success Rates for NCEs Also Vary by Therapeutic Class



Source: Tufts CSDD Impact Report, 8(3): May/June 2006

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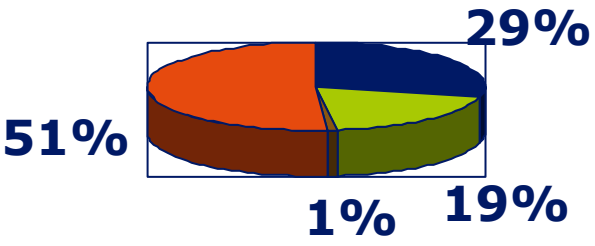
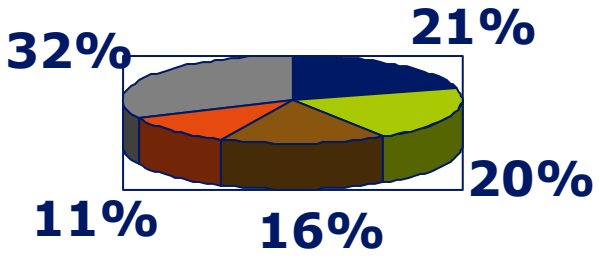
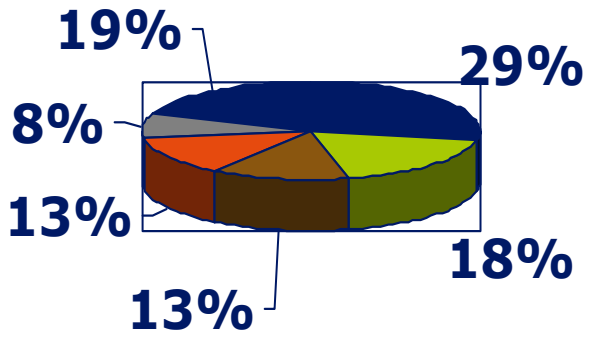
Phase II failures 2008-2010

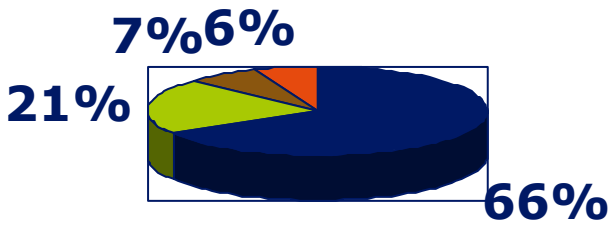




Source: Nature Review Drug discovery vol 10, May 2011

Phase III and submission failures 2007-2010





- Anti-cancer
- Nervous system
- Alimentary/metabolism
- Anti-infectives
- Cardiovascular
- Other

- Efficacy
- Safety
- Financial/commercial
- Not disclosed

Source: Nature Review Drug discovery vol 10, February 2011

New targets for drugs

- Sequencing the human genome and pathogen genomes has dramatically increased the number of targets for drugs
- but the biological knowledge is often limited increasing the risk…

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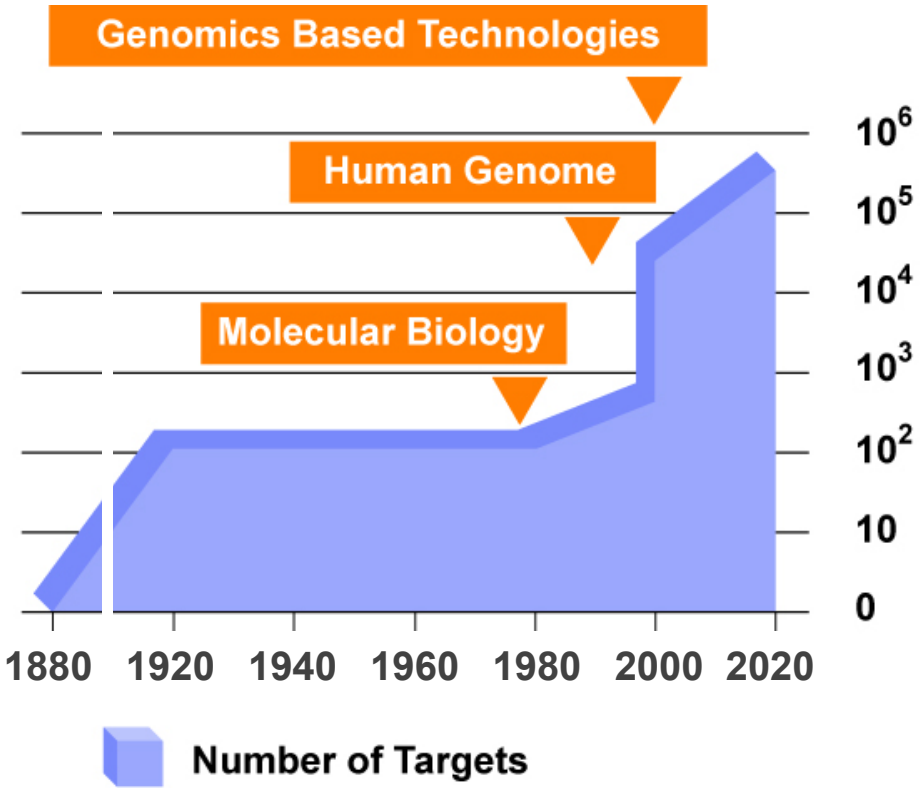
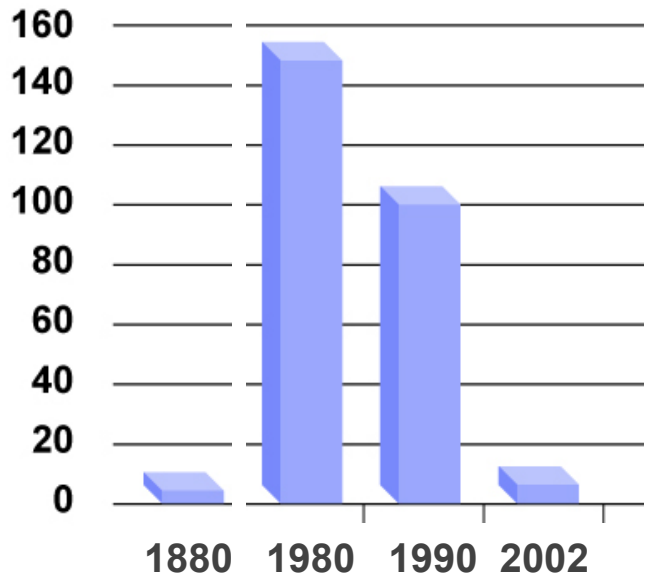
“Genomics” offer many targets but poor knowledge of each target



Number of Literature References Per Target**



* ** IBM Business Consulting Services Internal Research

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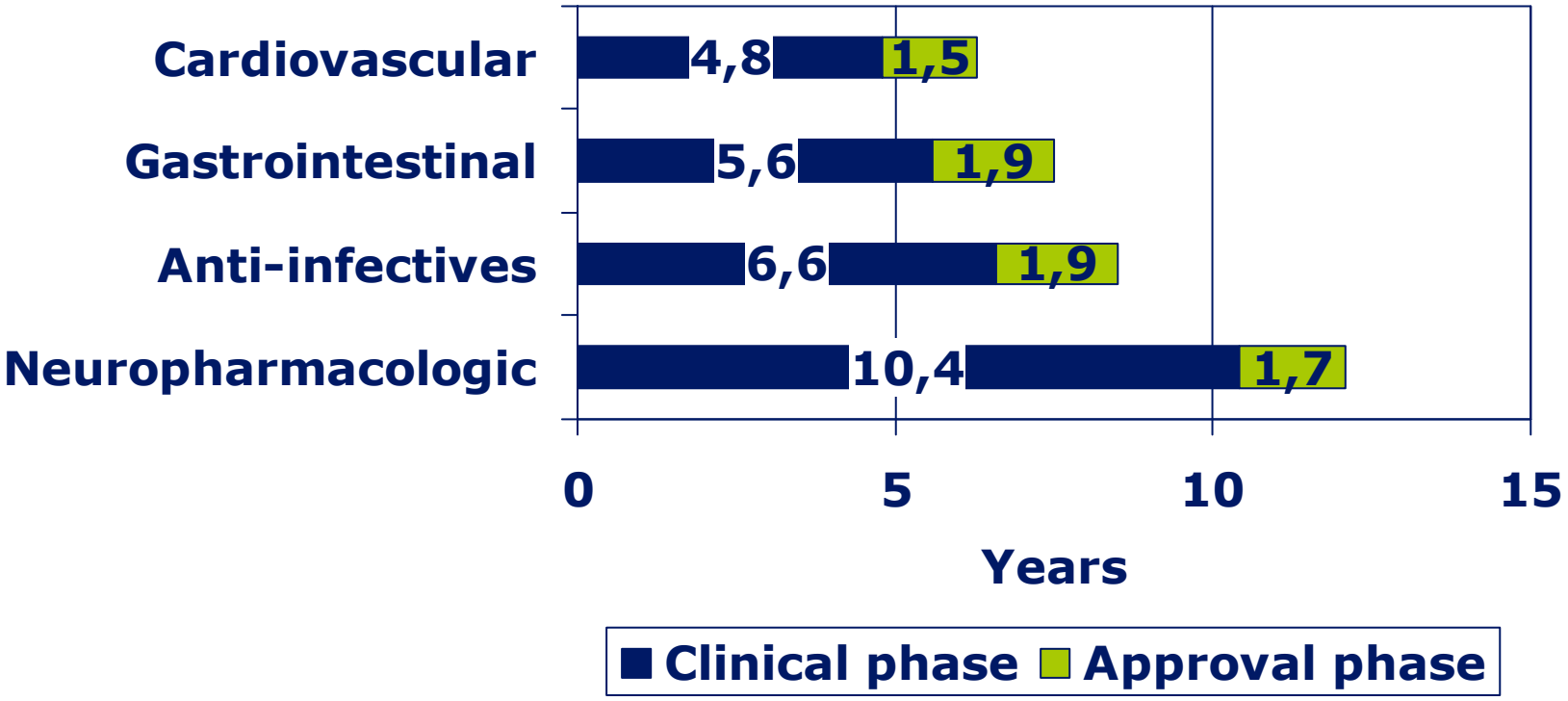
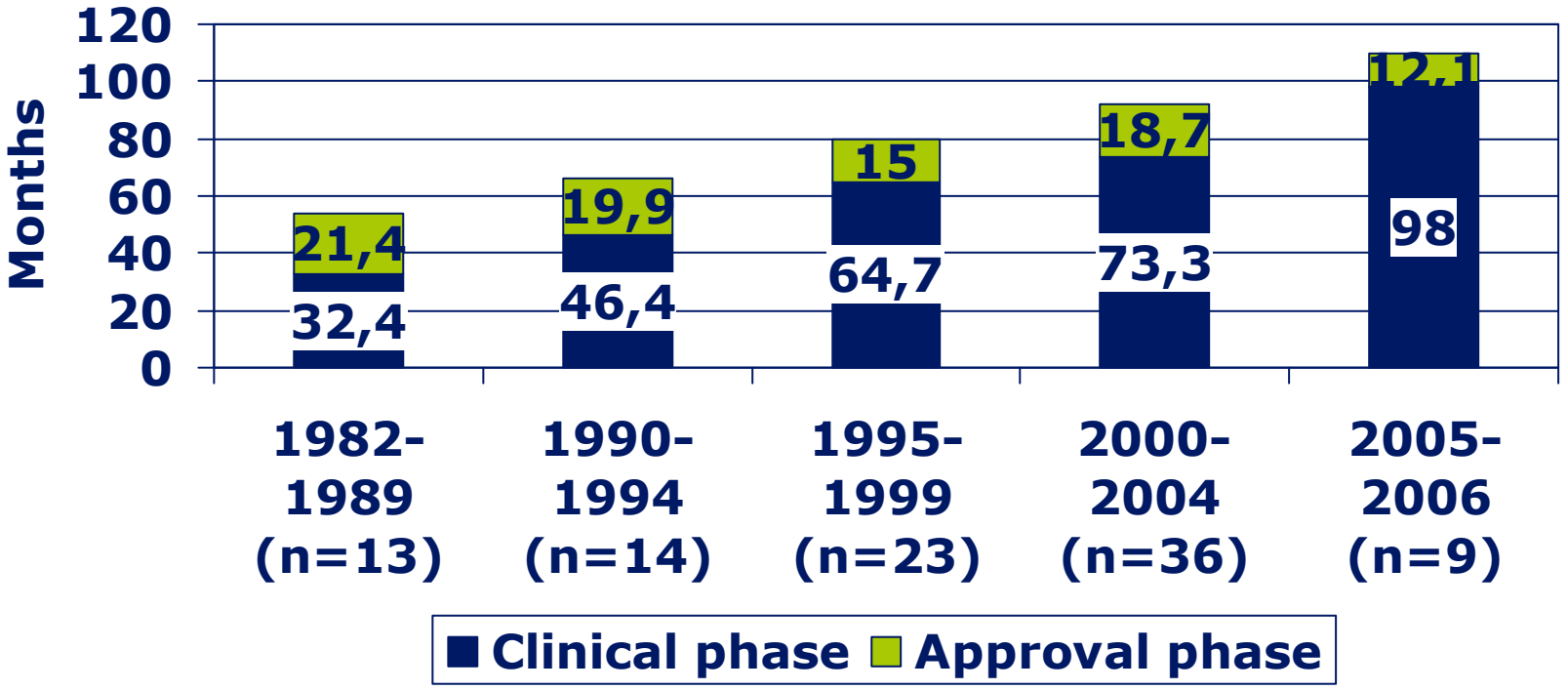
Clinical and approval times 2002-2004



Source: Tufts CSDD, 2006

Development times for new biological entities



Nature Reviews Drug Discovery **7**, 479-488 (June 2008)

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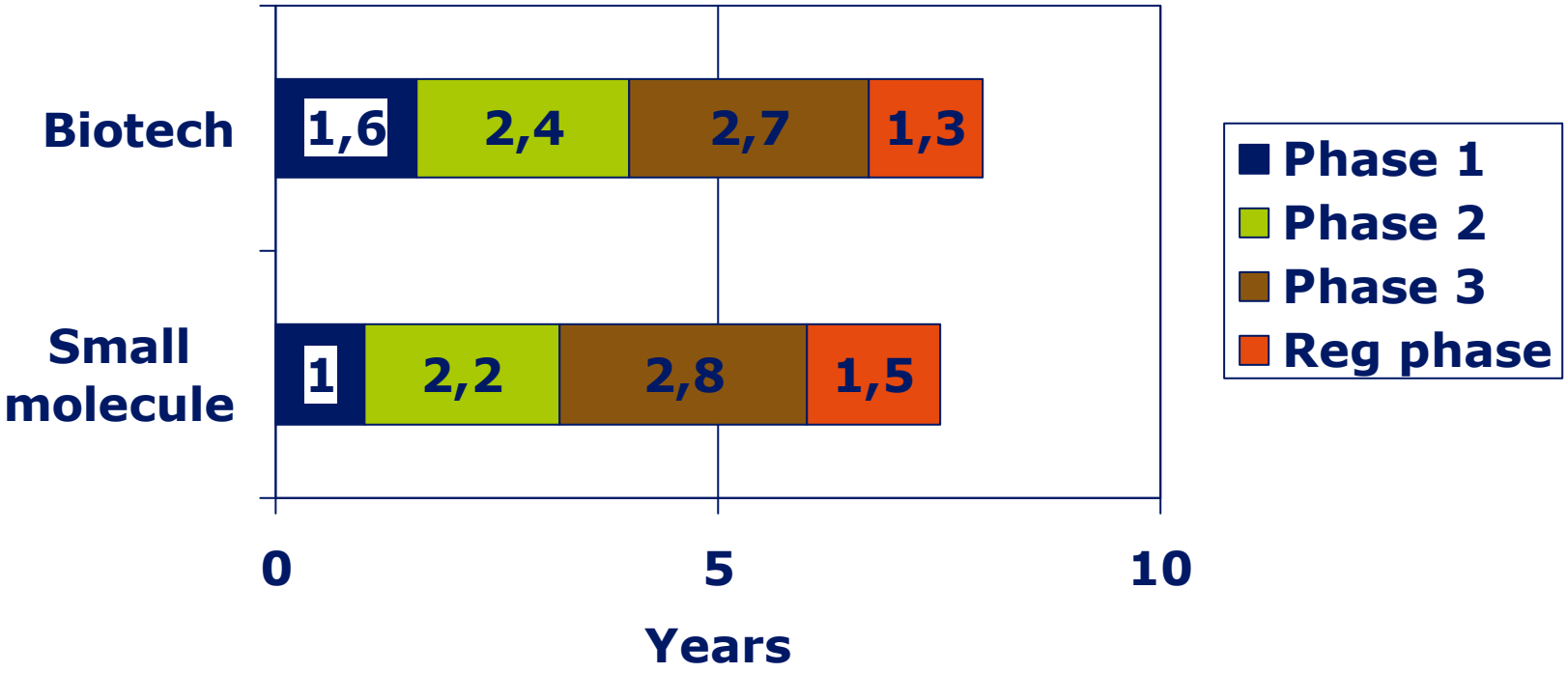
Biotech and small molecule development times are similar



Source: Tufts CSDD, 2006

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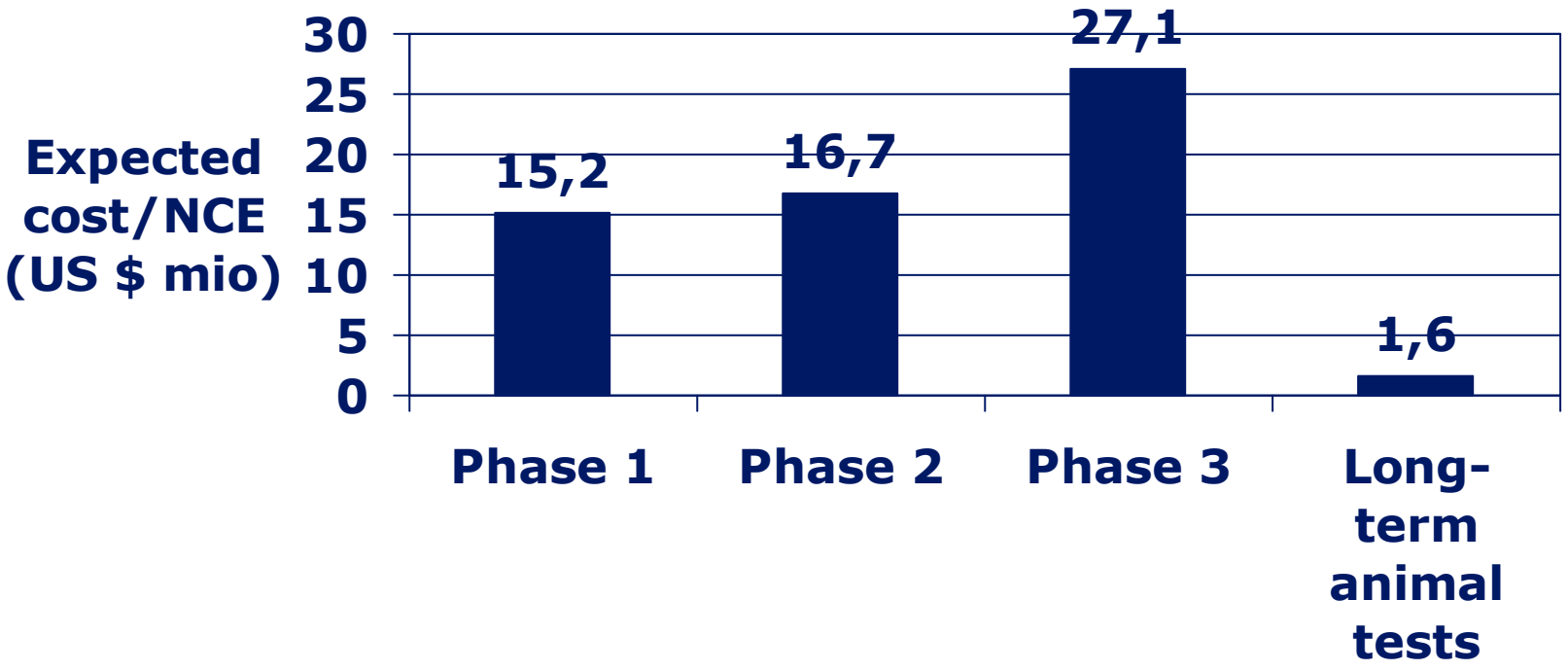
Cost of clinical testing of new chemical entities



Nature Reviews Drug Discovery **3**, 417-429 (May 2004)

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Drivers of rising clinical costs

- Chronic and complex indications
- Clinical trial size
- Patient recruitment/retention
- Regulatory demands
- Market oriented studies
- Late-stage attrition

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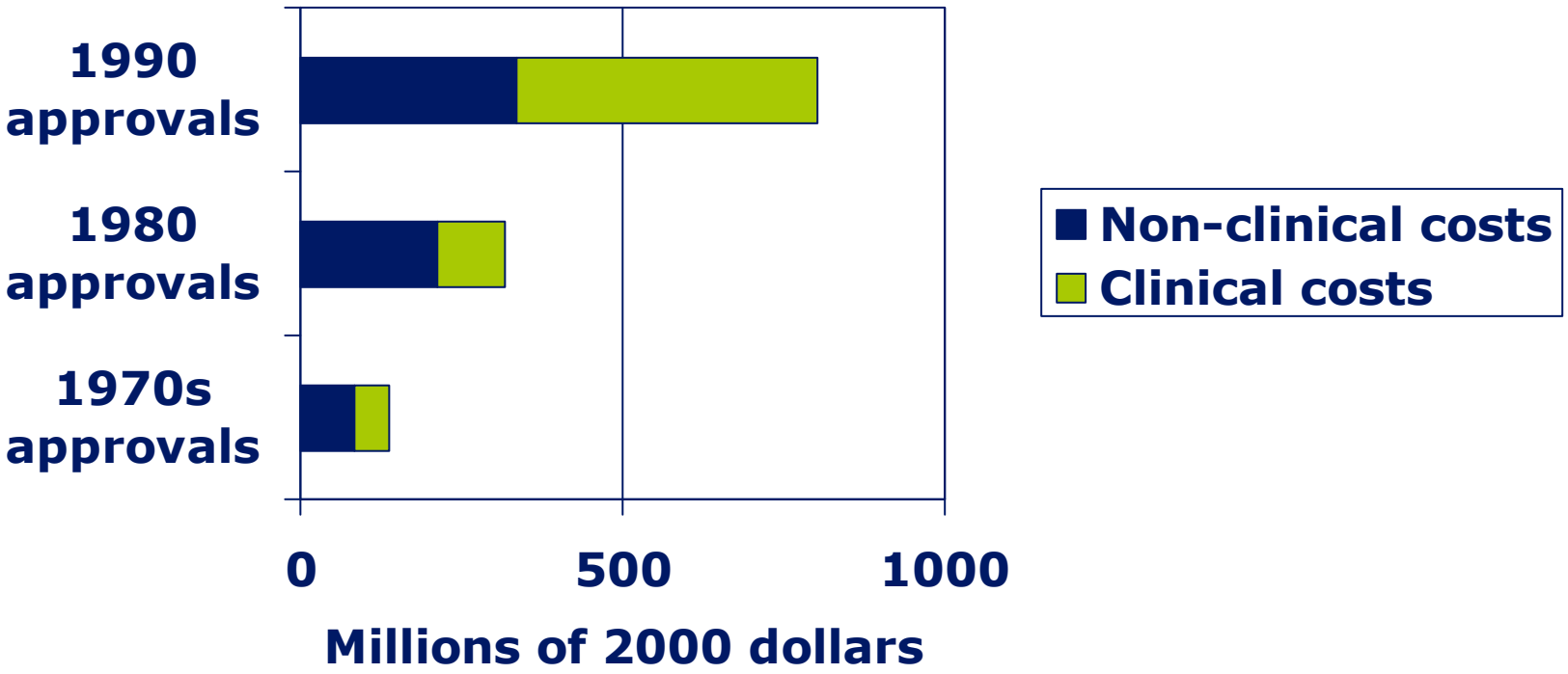
Dramatic increase in capitalized costs



Source: DiMasi et al., J Health Econ, 2003;22:151-185

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Drugs may be withdrawn after approval

Drug	Company	Year	Adverse effect	Patient claims	Litigation
Rezulin	Warner-Lambert (Pfizer now)	2000	Liver failure	4.000 cases	$15 billion
Vioxx	Merck	20004	Heart attacks & failures	10.000 cases	$15-25 billion

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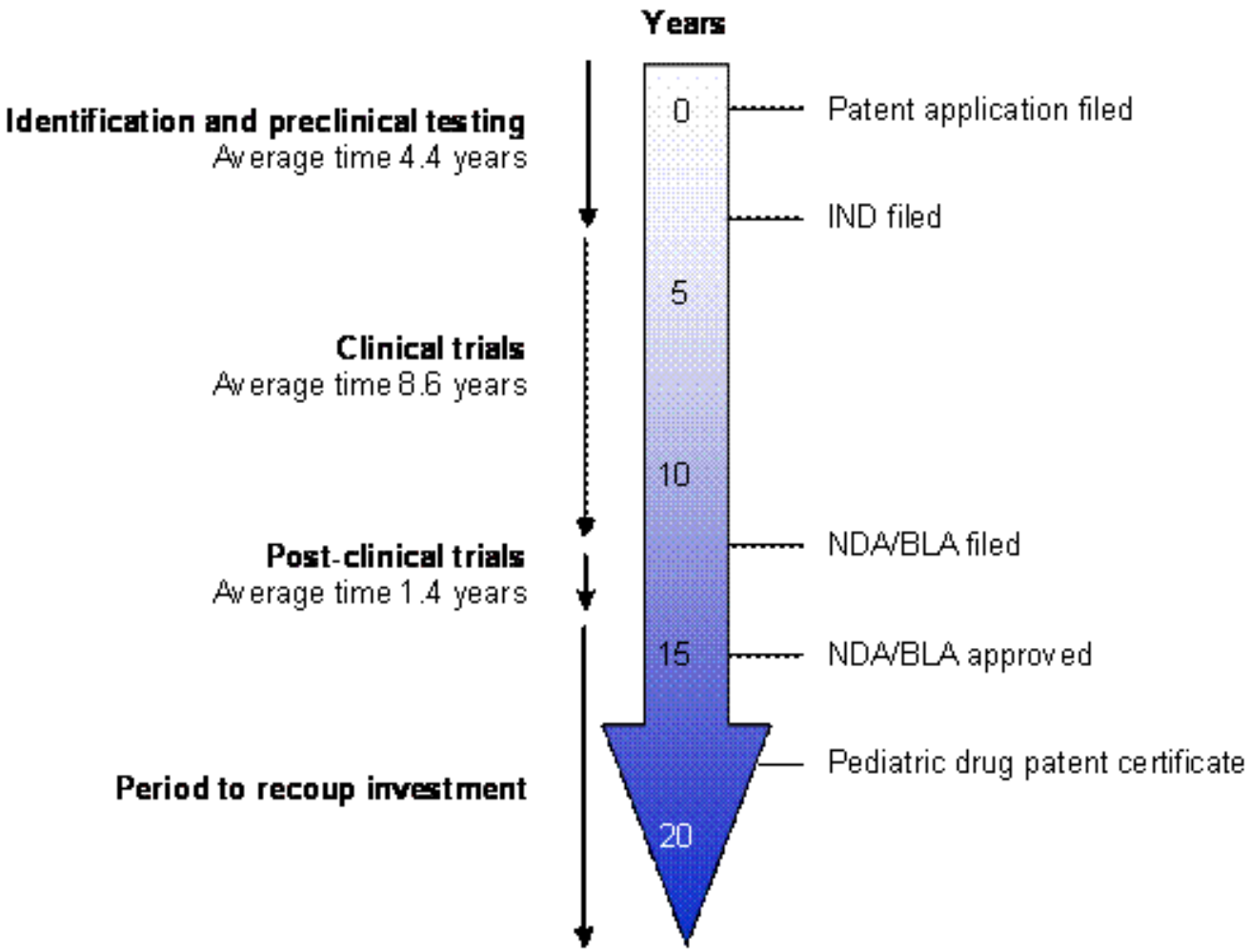
“Effective” patent life



- From: Winning R&D Productivity Strategies. Source: Business Insights; CMR; FDA
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Increasing patent vulnerability

	% of 1990 sales with patents expiring between 1990-1994	% of 1995 sales with patents expiring between 1995-1999	% of 2000 sales with patents expiring between 2000-2005
Europe	8%	14%	25%
US	10%	10%	19%

Source: Company Data and Goldman Sachs Research estimates

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Product profile important

- Today, a drug needs to have a competitive product profile (in relation to efficacy, safety and/or convenience) in order to get market share and to get reimbursement from national authorities.
- Efficacy and strategic reasons are probably the main attrition factors today.

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Challenges in the Pharma Industry

- Low R&D success rates
- High R&D costs
- Patent expiries
- Short lifecycles for new products
- Increased competition
- Health reforms (cost containment, generics)
- Few blockbusters (<4% of products generate sales of $500 million or more)

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